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December 9, 2022

Via ECF

The Honorable Nicholas Garaufis
The Honorable Marcia Henry, Magistrate Judge
United States District Court for the Eastern District of New York
225 Cadman Plaza East, Room 1426 S
Brooklyn, NY 11201

Re: *In Re: Exactech Polyethylene Orthopedic Products Liability Litigation*, MDL No.: 3044,
1:22-md-0344-NGG-MMH

Dear Judge Garaufis and Magistrate Judge Henry:

This letter is filed in response to the Court's December 6, 2022 Order directing Plaintiffs to submit a brief summary of the structure of the committees and subcommittees, and the purpose and membership of each such committee and subcommittee proposed in Plaintiffs' Motion to Appoint Counsel in this orthopedic device MDL involving total knee replacement systems, total hip replacement systems, and total ankle replacement systems.

Background

Until recently,¹ Exactech manufactured three primary knee systems made with moderately crosslinked ultra-high weight molecular polyethylene ("UHMWPE"): the (1) Optetrak, (2) Optetrak

¹ On November 4, 2022, Exactech announced it had received FDA 510(k) Clearance for its TriVerse Primary Knee Replacement System manufactured with highly crosslinked vitamin E-stabilized polyethylene. See Exactech Announces FDA 510(k) Clearance of the TriVerse Primary

Logic, and (3) Truliant. Each of the knee systems has multiple polyethylene tibial insert components that are at issue in this litigation (not to mention, other Exactech components used in the total knee system implanted in Plaintiffs). For example, the original Optetrak system has 13 different tibial components, the Optetrak Logic has six, and the Truliant has five tibial components.² There is one primary ankle replacement system at issue, Exactech's Vantage replacement system.³

Exactech likewise has seven products within its hip line that were made with moderately crosslinked and conventional UHMWPE including the Acumatch GXL, MCS GXL, Novation GXL, Exactech All Polyethylene Cemented Cup, Acumatch Conventional UHMWPE, MCS Conventional UHMWPE, and Novation Conventional UHMWPE.⁴ Initially only the Connexion GXL liner was quietly recalled for a risk of edge-loading and premature prosthesis wear in June 2021.⁵ A year later, on August 11, 2022 Defendants recalled the UHMWPE acetabular hip liners for its Connexion GXL, AcuMatch, MCS, and Novation hip systems implanted since 2004 stating they were packed in out-of-specification vacuum bags that lacked an ethylene vinyl alcohol barrier that was to prevent oxygen resistance.⁶ The recall letter to healthcare providers also acknowledges Exactech's moderate cross-linking material "is inherently more susceptible to oxidation and polyethylene wear in the hip versus modern, highly cross-linked Vitamin E polyethylene liners."⁷ Exactech's Vitamin E hip liner received FDA clearance in March 2018.⁸ Each product has different FDA regulatory submissions, different design histories, testing, and post-market surveillance.

In complex mass-tort MDL cases such as this, it is customary and helpful to establish multiple committees. This is particularly the case here where there are multiple products at issue, each with distinct design and manufacturing elements, different injuries and some differing witnesses and documents. Exactech's hip, knee, and ankle systems were manufactured and processed in different ways, and utilized multiple outside vendors for various manufacturing processes including compression molding, annealing, irradiation, machining, and packaging. Thus, Plaintiffs anticipate pursuing significant third-party discovery in this MDL.

Knee Replacement System (Nov. 4, 2022) available at <https://www.exac.com/wp-content/uploads/2022/11/Exactech-Announces-FDA-510k-Clearance-of-the-TriVerse-Primary-Knee-Replacement-System-1.pdf> (last visited Dec. 8, 2022).

² See Exactech Urgent Medical Device Correction Health Care Provider Letter for Knees and Ankles (Apr. 7, 2022) available at <https://www.exac.com/product/exactech-dhcp-letter/> (last visited Dec. 8, 2022).

³ *Id.*

⁴ See [Updated] Exactech Urgent Medical Device Correction Health Care Provider Letter for Hip Liners (Aug. 11, 2022) available at <https://www.exac.com/wp-content/uploads/2022/08/US-DHCP-Letter FINAL 8.09.2022 Hip.pdf> (last visited Dec. 8, 2022).

⁵ Class 2 Device Recall Exactech Connexion (June 29, 2021) available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=188099> (last visited Dec. 9, 2022).

⁶ See fn. 4.

⁷ *Id.*

⁸ Exactech's Vitamin E Acetabular Polyethylene Liner for Hip Replacement Gains FDA 510(k) Clearance, (Mar. 19, 2018), available at <https://www.exac.com/exactechs-vitamin-e-acetabular-polyethylene-liner-for-hip-replacement-gains-fda-510k-clearance/> (last visited Dec. 9, 2022).

It is further worth noting that although Exactech Inc. and Exactech U.S., Inc. are the primary defendants⁹ in this litigation, it is anticipated additional defendants will be added. Plaintiffs advise the Court of this now to assist the Court in appreciating that this litigation will grow in the upcoming months.

Proposed Committee Structure

1. Executive Committee

The proposed Executive Committee will consist of the two Co-lead counsel and three members of an Executive Committee who will assist in managing the litigation and supporting Co-lead counsel with overall case strategy, developing and implementing a litigation plan, managing discovery, conducting many of the principal examinations of deponents, employing experts, arranging for support services, and ensuring that schedules are met. Importantly, the Co-lead counsel with Executive Committee members will, at the appropriate time, engage in any settlement discussions. *See* MANUAL FOR COMPLEX LITIGATION (FOURTH) (“MCL FOURTH”) Section 10.221. Because there are multiple orthopedic devices at issue, Plaintiffs propose each Executive Committee member oversee the litigation of each device as outlined further below.

2. Liaison Counsel

Working closely with the PEC, the Proposed Liaison Rayna Kessler counsel would be responsible for administrative aspects of the case including maintaining overall leadership common benefit time and expenses and financial accounts, communications between the Court and other counsel, convening meetings of counsel (including leadership and Plaintiffs’ counsel who are not a part of leadership), advising parties of developments, and otherwise assisting in the coordination of activities and positions. As tasked by the Court, Ms. Kessler will also be responsible for maintaining a website containing relevant pleadings and Orders that is accessible to parties and their counsel and she has already started working on securing a host for the site. Ms. Kessler will also assist with pro hac applications and answering questions any attorneys may have as to MDL procedures.

3. The PSC

The proposed Plaintiffs’ Steering Committee is composed of twelve attorneys who will focus on different and specific aspects of the litigation and support the Executive Committee in prosecuting the case. The Steering Committee members will assist with discovery, (including preparing for and taking depositions, document review, privilege and redaction challenges, ESI issues, third-party discovery), drafting Master pleadings and legal briefing, negotiating proposed orders with defendants, science and experts, bellwether selection and case-specific discovery, accumulating and analyzing plaintiff profile information, investigating issues that will impact the overall litigation such as the financial viability of defendants, the private equity purchase, explant preservation protocols and ultimately trying cases. Certain PSC members will also be Committee Chairs and work under and at the direction of Lead Counsel and the Executive Committee and will be responsible for

⁹ TPG Inc. or TPG Capital LP are named Defendants in two cases in this MDL, *Minerva Salazar v. Exactech Inc.*, Case No. 1:22-cv-06455 (EDNY) (naming TPG Inc.); *Berger v. Exactech, Inc. et al.*, Case No. 1:22-cv-06449 (EDNY) (naming TPG Capital LP).

assigning and supervising the work of the sub-committees and report to the Executive Committee.

4. The Sub-Committees

The proposed Subcommittee Members will work under the direction of the PSC member Committee Chairs with respect to work within the scope of those committees. The proposed Subcommittees serve multiple purposes. Importantly, these Subcommittees give younger attorneys an opportunity to receive their first leadership appointments and gain valuable MDL leadership experience. Additionally, the Subcommittees allow smaller firms to participate in leadership with a smaller financial contribution, and allow attorneys who work at the same firm as the proposed Co-leads an opportunity to be acknowledged for the valuable work they do and significant time they spend advancing the MDL at the direction of their colleagues, Ellen Relkin and Kirk Pope.

Proposed Federal-state liaison counsel

Joseph Saunders will keep the Court apprised of developments in the consolidated Florida litigation against Exactech and will assist the Court with any information it needs in those matters.

Financial Aspects of Committees

Plaintiffs MDL structure is comparable to the running of a litigation law firm, but here, attorneys work jointly in prosecution of cases on behalf of clients throughout the country. The funding of a Plaintiff MDL leadership team comes from its members. Thus, behind these litigation roles lies another critical role for plaintiffs' leadership: adequately funding the litigation. In other orthopedic device litigations, Plaintiffs' leadership has historically advanced large funds for litigation expenses. Known and ongoing expenses include paying an electronic discovery vendor to host the documents, costs associated with taking depositions, hiring a claims administration firm for profile forms, identifying key characteristics of each case, and retaining and working with experts across multiple disciplines (including but not limited to biomechanical engineering, orthopedics, packaging, pathology, regulatory, and polymers). Later expenses potentially include mediators, trial costs, and potentially settlement administration and lien resolution services. The 27-person proposed leadership is necessary to ensure that the plaintiffs are not at a disadvantage in funding pretrial discovery and trials. Plaintiffs believe the proposed leadership structure will balance the competing goals of adequately staffing and funding the litigation, while ensuring proficiency and efficiency.

The breakdown of the roles and responsibilities for the proposed Plaintiffs' leadership is as follows:

I. Executive Committee

1. Ellen Relkin – Co-Lead Counsel¹⁰

¹⁰ In the event the Court was concerned that Ellen Relkin was too committed to other litigations by virtue of her current role as one of four co-leads of the *In Re: Juul Litigation* pending in the N.D.Cal., a global settlement of the litigation against JUUL was just announced this week. <https://www.nytimes.com/2022/12/06/health/juul-settlement-lawsuits-teen-vaping.html>

2. Kirk Pope – Co-Lead Counsel
3. Robert E. (Eric) Kennedy – Head of Knee Litigation
4. Carasusana B. Wall– Head of Ankle Litigation¹¹
5. Calvin Warriner– Head of Hip Litigation

II. Liaison Counsel – Rayna Kessler

III. Federal/State Liaison Counsel– Joseph Saunders

IV. Plaintiffs’ Steering Committee and Subcommittee Members:

Below is an outline of the PSC and Subcommittee Members that would serve on each Subcommittee.

A. Law and Briefing: (Drafting pleadings, research, and motion practice)

1. David Harman- Committee Chair
2. Justin Presnal
3. Mark P. Chalos
4. Joannah Oh*

B. Science and Experts: (Accumulating and updating scientific literature library, work with experts in the development of extracted medical device preservation, retaining appropriate experts across multiple disciplines, liaising with experts and providing them with necessary discovery materials, initially responsible for coordinating expert reports and any rebuttal expert reports in response to Defendants’ expert reports, and participating in any *Daubert* motion practice).

1. Hadley Lundback – Committee Chair
2. Daniel A. Nigh
3. Patrick J. Wigle
4. Danielle Gold*
5. Ilana S. Wolk*

C. Discovery: (Document review, preparation of interrogatories and document demands, preparing for and taking fact depositions, document privilege and redaction challenges, ESI issues, third-party discovery, maintaining a document repository, organizing documents by category and relevance)

1. Michael P. Cutler – Committee Chair
2. Ben C. Martin
3. Maria Fleming
4. Jason Goldstein

¹¹ While the JPML did not originally include Exactech ankle cases in the MDL scope, they have since transferred at least two cases. Dunleavy, Paul and Wendy (3:22-cv-06305), MDL Case Number 1:22-cv-06987 and Vol Euler, Sharon and Bjorn, MDL case number 1:22-cv-07197.

5. Kevin M. Fitzgerald*
6. George E. McLaughlin*
7. Courtney L. Mohammadi*
8. Cameron J. Falcon*

D. Bellwether: (Review Plaintiff data analytics including plaintiff profile information for bellwether selection, coordinate with individual Plaintiff's counsel in obtaining pertinent medical records in evaluation of claims, coordinate, supervise and as appropriate handle individual Plaintiff bellwether discovery, recommend to Executive Committee representative cases for bellwether selection for trial tracks involving hips, knees and if appropriate, ankles)

1. Kristine K. Kraft- Committee Chair
2. Carasusana Wall
3. Craig M. Silverman*
4. Arati Chauhan Furness

* Denotes Subcommittee member

If the Court would like any additional information or has any questions, Plaintiffs' proposed leadership are happy to address them in writing or appearing before the Court.

Respectfully submitted,

/s/ Ellen Relkin, Esq.
Weitz & Luxenberg, P.C.
700 Broadway
New York, NY 10003

-and-

/s/ Kirk Pope, Esq.
Pope McGlamry
3391 Peachtree Road, #300
Atlanta, GA 30326

(Plaintiffs' Proposed Co-lead Counsel)

cc: All counsel of Record via ECF